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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/542,435

05/02/2006

Jeffrey D. Rothstein

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28213 7590 05/12/2011  
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EXAMINER

MACFARLANE, STACEY NEE

ART UNIT

PAPER NUMBER

1649

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/542,435	<b>Applicant(s)</b> ROTHSTEIN ET AL.	
	<b>Examiner</b> STACEY MACFARLANE	<b>Art Unit</b> 1649	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 March 2011.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 2, 19 and 45-48 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2, 19 and 45-48 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/7/2011</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Formal Matters***

1. No claim amendments have been made. Claims 2, 19 and 45-48 are pending in the instant application and are under examination in the instant office action.
2. Applicant's arguments filed on March 7, 2011 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2, 19 and 45-48 stand as rejected under 35 U.S.C. 103(a) as being unpatentable over Rothstein et al., WO0130968 (2001) in view of Wahle et al. (1996) for reasons of record in the previous Office action.

On pages 4-6 of Remarks filed March 7, 2011, Applicant argues that the invention is based on the seminal discovery that GTRAP3-18 acts as a general regulator of cellular glycosylation as opposed to modulating glutamate transporters in general. Applicant further argues "Rothstein fails to disclose the ability of GTRAP3-18 to regulate glycosylation of a number of neurotransmitter transporters and receptors including glutamate transporters dopamine transporters, GABA transporters, and amino acid transporters" and, therefore, "Rothstein does not disclose the method of the instant

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invention for identifying compounds that are capable of generally modulating cellular glycosylation" (Remarks, top of page 6). Applicant further argues that Wahle fails to remedy the deficiencies of Rothstein by failing to disclose the claimed method because the Rothstein reference "is silent as to the function of GTRAP3-18 as a general regulator of cellular glycosylation" and Wahle is silent as to GTRAP3-18.

This is not found persuasive for the following reasons. Applicant is arguing elements that are not claimed. The method of the invention does not require regulation of cellular glycosylation in general. Nor does it require detection of "a number of neurotransmitter transporters and receptors including glutamate transporters dopamine transporters, GABA transporters, and amino acid transporters". Rather the claim is specifically drawn to detection of GLAST/EAAT1 glycosylation and the prior art teaches that EAAT1 glycosylation was known and that GTRAP3-18 modulation of glutamate transport was also known.

The Examiner maintains that the Rothstein publication teaches methods of "identifying a compound that modulates a cellular response mediated by a Glutamate Transporter Associated Protein" (GTRAP) as required by the claim, by identifying a "compound that inhibits an interaction between a GTRAP and a glutamate transporter protein". Rothstein et al. teach that GTRAP3-18 modulates transporter activity and discloses methods wherein the GTRAP polypeptide is the rat GTRAP3-18 protein which is identical to SEQ ID NO: 2 of instant claim 46 and the nucleic acid sequence of SEQ ID NO: 1 (Claim 47) (see Rothstein Figures 18 and 19).

The only element that the Rothstein is silent is with respect to the step requiring “detecting the level of glycosylation of a GTRAP3-18 target molecule ... wherein the GTRAP3-18 target molecule is glutamate transporter GLAST/EAAT1”. The Wahle et al. prior art teach methods for detecting the glycosylation state of the GLAST1 transporter and explicitly discloses that it was well-known in the art at the time of filing that the glycosylation state of GLAST1/EAAT1 transporter intimately affects transporter activity.

The Examiner maintains that *KSR International Co. v. Teleflex, Inc.*, the Supreme Court has stated that combining prior art elements according to known methods to yield predictable results is *prima facie* obvious. Based upon the guidance and direction within the Rothstein and Wahle prior art references, such combination would have been well within the technical grasp of a skilled artisan. It would have been obvious to one of ordinary skill to detect the level of glycosylation level since Wahle et al. art explicitly teaches that glycosylation affects GLAST transporter expression and activity. Thus, using the elements of the known methods, one of ordinary skill in the art would have been able to predictably combine the elements with a reasonable expectation of success of determining the level of glycosylation of GLAST/EAAT1 proteins in the presence of GTRAP3-18 and test compounds. Examiner maintains that the invention as a whole is *prima facie* obvious.

### ***Conclusion***

4. No claim is allowed.
5. **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to STACEY MACFARLANE whose telephone number is (571)270-3057. The examiner can normally be reached on M-R 5:45 to 3:30, TELEWORK-Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ali Salimi can be reached on (571) 272-0909. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Stacey MacFarlane  
Examiner  
Art Unit 1649

/Lorraine Spector/  
Primary Examiner, Art Unit 1647